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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,764	03/31/2004	Eric R. First	17672 (BOT)	8867

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,764	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

1. Claims 1-5,7-11, 13 are rejected under 35 U.S.C. 112, first paragraph (scope), because the specification, while being enabling for a method of treating or preventing a pressure sore defined to include methods that alleviate at least one symptom associated with a pressure sore, specifically those effects that adversely effect skin due to muscle tension, through administering a specific non-toxic dosage of botulinum neurotoxin, delivered locally to the cite which effects the symptom to be alleviated, does not reasonably provide enablement for the administration of any dosage size to any local location of a mammal in a method of treating any pre-existing pressure sore or preventing any skin area that is predisposed to developing a pressure sore, has been obviated in light of the amendment of the claims to recite the phrase "therapeutically effective amount".

Rejections Maintained

1. Claims 1-4, 6-10, 12-13 rejected under 35 U.S.C. 102(b) as being anticipated by Pohl et al, is maintained for reasons of record and responses set forth below.

2. Claims 1-3, 6-9, 12, and new claim 14 under 35 U.S.C. 102(b) as being anticipated by Kennedy, (1997), is maintained for reasons of record and responses set forth below.

3. Claims 1-12 rejected under 35 U.S.C. 102(b) as being anticipated by Gassner et al (US Pat. 6,44,787) is maintained for reasons of record and responses set forth below.

Response to Arguments

1. Applicant's arguments filed May 2, 2005 have been fully considered but they are not persuasive.

4. The rejection of claims 1-4, 6-10, 12-13 under 35 U.S.C. 102(b) as being anticipated by Pohl et al is traversed on the grounds that the "cited references do not disclose, teach, or even suggest locally administering a botulinum toxin to treat a pressure sore or prevent the development of a pressure sore without substantially paralyzing a muscle."

5. It is the position of the examiner that upon consideration of the narrative at page 23, lines 14-18, to which Applicant points as support for the instantly claimed invention, the examiner found that paralysis of a muscle is encompassed by the instant invention when the pressure sore is "related to contractures or spasticity (see instant Specification, page 23, lines 14-15). Therefore, within the scope of what is now claimed is the treatment of pressure sores caused by spasticity through paralyzing a muscle. What is now claimed does not exclude the treatment of patients with spasticity or contractures in order to treat/prevent pressure ulcers/sores.

6. The Specification defines two exceptions where paralyzing a muscle is the preferred mode of treating a pressure sore, specifically when the pressure sore is related to contractures or spasticity. Pohl et al treated a patient with pressure sores (ulcers) caused by spaticity with botulinum toxin. Therefore, Pohl et al treated a pressure sore patient through muscle paralysis, which is within the definition of Applicant's invention set forth at page 23, lines 14-18, the scope of which Applicant asserts is the scope of what is now claimed (see Applicant's Remarks Introduction section page 5 of 9, first

paragraph, last two lines.) The rejection of claims 1-4, 6-10 and 12-13 is maintained for reasons of record and responses set forth above.

7. The rejection of claims 1-3, 6-9, 12, and new claim 14 under 35 U.S.C. 102(b) as being anticipated by Kennedy, (1997) is traversed on the grounds that:

"Kennedy et al does not disclose, teach or even suggest administration of a botulinum toxin to treat or prevent a pressure sore without substantially paralyzing a muscle."

8. It is the position of the examiner that Kennedy discloses the instantly claimed invention because the reference discloses the administration of botox, a botulinum toxin "By using it in small amounts, it can be injected directly into spastic muscles, where the nerve attaches to the muscle, blocking the signal", wherein the amount of toxin administered "controls the spasm, but totally like a nerve block (see page 22, col. 2, paragraph 3"). The patients treated that are most likely to develop pressure sores evidence cramping, the cramping resulting in making the patients "immobile (see page 22, col. 1, last paragraph)". Through administration of botulinum toxin to elevate the cramping and spasticity, the preventing a pressure sore is achieved (see page 22, col. 1, last paragraph "Cramping can make patients terribly uncomfortable and can make them immobile, leading to pressure sores"). The reference still anticipates the instantly claimed invention.

9. The rejection of claims 1-12 under 35 U.S.C. 102(b) as being anticipated by Gassner et al (US Pat. 6,44,787) is traversed on the grounds that: "Gassner et al

specifically discloses injecting muscles with botulinum toxin to paralyze the muscles to reduce tension on a surgical wound".

10. While the examiner agrees that Gassner et al does inject botulinum toxin to enhance wound healing, the amount of botulinum toxin was only 7 units and 20 units of botulinum toxin, and instant claims 4 and 10 administer between 1 and 25,000 units of botulinum toxin. Clearly the amount of Gassner et al is at the lower end of the number of units of botulinum toxin now claimed and would therefore not substantially paralyze the muscle(s) to which it was administered.

While Gassner et al does not teach the phrase "without substantially paralyzing a muscle", Gassner et al does administer a botulinum toxin in the amounts claimed by Applicant in the amended claims (see claims 4, and 10). Therefore Gassner et al inherently discloses the claimed invention because by all comparable data (the toxin administered, the amount of toxin, and the patient population treated) the method of Gassner et al is the same or equivalent method claimed by Applicant.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states AArtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the

discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.

New Claims/New claim limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All of the claims have been amended to recite the phrase "without substantially paralyzing a muscle" which has been asserted to find original descriptive support in lines 14-18 on page 23 of the instant Specification.

13. The examiner upon consideration of the narrative found at page 23, lines 14-18, could not find the phrase "substantially paralyzing a muscle" at this location. The narrative found at page 23, lines 14-18 defines a genus of methods of treating a pressure sore that contains two exceptions related to contractures or spasticity, wherein when treating contractures or spasticity paralysis of a muscle is permitted, and when treating other conditions associated with pressure sores that do not involve spasticity or

contractures the dose of Clostridial toxin is less than the amount of toxin used to paralyze a muscle. The narrative at page 23, lines 14-18 permits administration of botulinum toxin to cause paralysis of a muscle or administration "not to paralyze a muscle" but does not provide original descriptive support for the instantly claimed genus of methods that administer any therapeutically effective amount of botulinum toxin "without substantially paralyzing a muscle". Original descriptive support for the instantly claimed combination of claim limitations could not be found in the instant Specification, and therefore all amended claims contain New Matter.

14. All of the claims are rejected under 35 USC 112, second paragraph. The term "without substantially paralyzing a muscle" in all of the claims seeks to define a subgenus of species of methods defined by the recited phrase that includes a relative term ("substantially paralyzing") which renders the claim indefinite. The term "substantially paralyzing" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. See discussion of this phrase immediately above under 35 USC 112, first paragraph.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Voller et al (2001, abstract) is cited to show that administration of botulinum toxin for the treatment/prevention of pressure sores.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
August 8, 2005

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